REMARKS

The following remarks are made in response to the Office Action mailed November 19, 2009. Claims 24 and 25 have been previously withdrawn from consideration. Claims 1, 3-5, 10, 12-23, 32 and 53-55 were rejected. With this Response, claims 54 and 55 have been cancelled and claims 1, 10, 32 and 54 have been amended. No new claims have been added. Claims 1, 3-5, 10, 12-23, 32, and 5354 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 112

Claims 10, 32, 54 and 55 have been rejected under 35 U.S.C. §112, ¶2 as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicants regard as the invention.

Claim 10 has been amended to depend from Claim 1. Claims 32 and 54 have been amended to provide for the appropriate antecedent basis. Claim 55 has been cancelled.

Applicants, therefore, respectfully assert that these rejections under 35 U.S.C. §112, ¶2 should be withdrawn.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 3-5, 10, 12-23, 32, and 53-55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application No. 2003/0154974 to Morgan ("Morgan").

The Examiner states that Morgan discloses a fiber composition having the molecular weight as claimed. The Examiner acknowledges that Morgan does not report the viscosity or fat content but states that the fiber composition in Morgan is prepared by substantially the same method as the claimed invention and the composition has a molecular weight within the range claimed, thus it would be obvious that the composition will have the same viscosity as claimed.

The Applicants respectfully disagree with the Examiner's statements.

Claim 1 recites a dietary fiber composition isolated from a cereal grain containing β-glucan, comprising: a β-glucan composition having a weight average molecular weight ranging from about 120 kDa to about 400 kDa, wherein a 1% mixture by weight of said dietary fiber composition and water is stable and has a viscosity of about 1500 cps or less, and wherein the dietary fiber containing material has a protein content of from about 1% to about 3% by weight. Claims 3-5, 10, 12-23 and 53 depend either directly or indirectly from claim 1.

Claim 32 recites a composition, comprising: a β-glucan composition in amount sufficient to lower LDL-C, wherein said β-glucan composition comprises a β-glucan compound having a weight average molecular weight ranging from about 120 kDa to about 250 kDa, and wherein said β-glucan composition has a viscosity less than or equal to about 100 cps, and a 1% mixture by weight of said composition and water is stable and has a viscosity of about 1500 cps or less, and wherein the β glucan composition has a protein content of from about 1% to about 3% by weight.

The weight average molecular weight of the β-glucan composition in the claimed invention is from about 120 kDa to about 400 kDa. As shown in the declaration by Dr. Richard Hess, the weight average molecular weight of the β-glucan composition produced according to the process disclosed in Morgan is well below this range. Although Morgan does not recite the molecular weight for each of the examples provided, this statement follows from Dr. Hess's analysis of the disclosed subject matter along with supporting references, many of which are authored by and reflect the work of Keith R. Morgan. This analysis supports the statement that one of skill in the art would recognize that the process taught by Morgan would not result in a modified β-glucan material with a molecular weight greater than 75 kDa. Further, Dr. Hess provides an explanation for the one data point in Morgan that at first glance would appear to fall within the weight average molecular weight range of the claimed invention. Briefly, this

explanation shows that this particular data point is clearly an outlier and not representative of or relevant to the claimed invention. It is instead a measurement of a native β-glucan material because no native enzymes were present during processing not a measurement of processed or hydrolyzed material.

This molecular weight distinction carries great significance. As described by Dr. Hess, clinical testing involving an investigation of the efficacy of a highly β-glucan enriched product, where the β-glucan product had a molecular weight of about 75 kDa, did not show clinically significant improvements in lipid or glucose control. This translated to no evidence of improvement in CVD or type 2 diabetes risk in this group of young to middle-aged, mildly hypercholesterolemic men. Further, it was reported that because β-glucan was previously shown to be highly efficacious at doses as low as 3 g/d, the lack of effect was considered to be, at least in part, a *consequence of structural changes in β-glucan* that result from the commercial processing of the barley into a highly enriched β-glucan product.

In stark contrast, the claimed invention is efficacious in affecting cardiovascular disease marks. As attested to by Dr. Hess and supported by the clinical study results conducted by Keenan, et al., there was a decrease in health benefits as the molecular weight of the β-glucan product fell below 150 ± 20 kDa. Subsequent work by Dr. Hess also indicates that there is an upper limit at which efficacy is maximized. The molecular weight range of from 120 to 400 kDa is consistent with these findings.

It would not have been obvious in view of the process or product disclosed by Morgan to maintain this molecular weight range. Morgan does not report a low molecular weight β-glucan product that can provide the reported health benefits. Morgan instead places great focus on hydrolysis of β-glucan of barley materials to obtain a β-glucan product having a molecular weight below 80 kDa to obtain unique gelling characterics. The claimed invention, however,

specifically controls the molecular weight of the β-glucan product to the range of 120 to 400 kDa to maintain the health benefits.

Accordingly, applicants respectfully submit that claims 1 and 32 and claims dependent therefrom are not obvious over Morgan, and request that the rejection be withdrawn.

Conclusion

In view of the above, Applicant respectfully submits that all pending claims are in form for allowance and are not taught or suggested by the cited reference. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1, 3-5, 10, 12-23, 32 is respectfully requested.

Applicants hereby authorize the Commissioner for Patent to charge Deposit Account No. 50-2342 to cover any necessary fees as set forth under 37 C.F.R. 1.16(h)(i).

The Examiner is invited to contact the Applicant's representative at the below-listed telephone number to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Gretchen Pesek Skarohlid at Telephone No. (942) 742-2571. In addition, all correspondence should continue to be directed to the following address:

Customer No.: 38550

CARGILL, INCORPORATED
Law Department
P.O. Box 5624
Minneapolis, MN 55440-5624
Facsimile No.: (952) 742-6349

Respectfully Submitted,

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/Gretchen Pesek Skarohlid/

GPS:gps

Gretchen Pesek Skarohlid

Registration No.: 54,372

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